

## **REMARKS**

Claims 1, 3-5, 7, 9, 10 and 13 are pending in this application. Claims 9 and 10 are canceled herein without prejudice. Claims 1, 7 and 13 are amended herein for clarity to more particularly define the invention. Support for these amendments is found in the language of the original claims and throughout the specification, as set forth below. No new matter is added by these amendments and their entry and consideration is respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

### **I. Priority**

The Office Action states that the status of the parent application is missing on the first page and that the provisional application number listed in the specification is not the same as the provisional application number on the bib sheet and oath.

The specification is amended herein to recite the status of the parent application and the correct provisional application number, thereby addressing the issues raised by the Examiner.

### **II. Rejection under 35 U.S.C. § 112, first paragraph (written description)**

A. The Office Action states that claims 1, 3, 5, 7, 9, 10 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement on the basis that the claims as amended introduce new matter. Specifically, the Office Action states that the specification does not disclose 1) "alveolar epithelial progenitor cells" as recited in claim 1; 2) "alveolar epithelial progenitor cells are lung cells" as recited in claim 9; or 3) "alveolar epithelial progenitor cells are bone marrow cells" as recited in claim 10.

Claim 1 as presented herein does not recite "alveolar epithelial progenitor cells," thereby mooting this rejection. Claims 9 and 10 are canceled herein without prejudice, thereby mooting this rejection as it pertains to these claims. Applicants therefore respectfully request withdrawal of this rejection.

B. The Office Action states that claims 1, 3-5, 7, 9, 10 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement on the basis that the claims contained subject matter not described in such a way in the specification to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. Specifically, the Office Action states that the rejected claims are readable on a genus of alveolar epithelial progenitor cells capable of regenerating lung alveolar surface, wherein the genus of progenitor cells is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made. The Office Action further states that the specification contemplates using a genus of progenitor or stem cells capable of regenerating lung alveolar surface and that a species of stem/progenitor cells exist in the distal lung and can regenerate both alveolar epithelium and capillaries and that the invention contemplates exploiting the properties of stem cells by stimulating them to divide and differentiate using soluble growth factors and other suitable growth factors. The Examiner then states that the specification only discloses *in vitro* embryonic day 12 (E12) lung cells cultured with FGF-10 and lung sections from embryonic and neonatal mice and hyperoxia treated adult rats express telomerase that plays a role in directional outgrowth and possibly induction of epithelial buds and AEC2 cells have been designated the primary progenitor cells of the alveolar epithelium. The Office Action goes on to state that the limitation in instant claims 9 and 10 indicates that the genus is broader than progenitor cells from lung cells or bone marrow cells and the art of record displays a table of stem cells and the type of cell types developed and none of the stem cells developed into lung cells. The Office Action then states that the specification does not disclose how to obtain or make a representative number of progenitor cells that can regenerate lung alveolar surface and that the claimed invention as a whole is not adequately described if the claims require essential critical elements that are not adequately described in the specification and that are not conventional in the art at the time of filing the instant application.

Claim 1 as presented herein recites a method of regenerating alveolar surface area in a lung, comprising: administering alveolar epithelial type 2 (AEC2) cells to said lung in an amount sufficient to regenerate alveolar surface area therein, wherein said alveolar epithelial type 2 cells

are from the same species as said lung. The specification provides adequate written support for this method, at least, for example, on page 8, line 30 through page 10, line 4 and in the Examples section wherein AEC2 cells are described. Furthermore, mammalian and human lungs as recited in claims 4 and 5 are described on page 9, lines 1-3; autologous cells as recited in claim 7 are described on page 9, line 12; and *ex vivo* methods as recited in claims 3 and 13 are described on page 9, lines 28-30. Claims 9 and 10 are canceled herein without prejudice, thereby mooted this rejection as it pertains to these claims. Thus, the claims of this invention are adequately described in the specification as filed to meet the written description standards and applicants respectfully request the withdrawal of this rejection.

### **III. Rejection under 35 U.S.C. § 112, first paragraph (enablement)**

The Office Action states that claims 1, 3-5, 7, 9, 10 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

Claims 9 and 10 are canceled herein without prejudice, thereby mooted this rejection as it pertains to these claims.

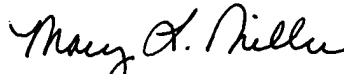
With regard to claims 1, 3-5, 7 and 13, it is applicants' position that these claims as presented herein are adequately enabled. In support of this position, applicants provide herewith a Declaration under 37 C.F.R. § 1.132 by co-inventor, Dr. Barbara Driscoll, which provides the results of studies carried out under her direction that demonstrate regeneration of alveolar surface area in a lung by engraftment of AEC2 cells in a mouse model.

Further provided herein are abstracts of various publications, which predate the filing date of this application, that demonstrate that the art of lung transplantation was sufficiently developed at the time this application was filed in 1999 to expect that transplantation as described in the claimed methods could be carried out using routine procedures. Applicants note that the Examiner points out on page 7 of the Office Action that the state of the art of cell and lung transplants was sufficiently developed at the time this application was filed and applicants submit that the statements in the Office Action demonstrate enablement of the present invention.

In particular, as the Examiner is aware, the standard for enablement is whether the claimed invention can be carried out by one of skill in the art without undue experimentation and there is no requirement that an invention address or overcome all obstacles in a field in order to be enabling. Thus, applicants provide ample evidence that the methods of the claimed invention are adequately enabled and therefore respectfully request the withdrawal of this rejection.

A check in the amount of \$60.00 is enclosed as fee for a one month extension of time for a small entity. This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0221.

Respectfully submitted,

  
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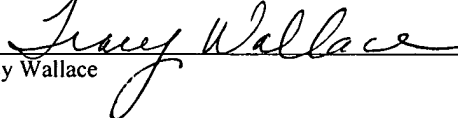
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Tracy Wallace